REMARKS

The Office Action of December 4, 2009, has been received and reviewed.

Claims 1-16 and 18-23 are currently pending and under consideration in the above-reference application. Each of claims 1-16 and 18-22 has been rejected.

Claim 23 has been objected to as being dependent upon rejected base claims, but the indication of allowable subject matter in claim 23 is noted with appreciation.

Reconsideration of the above-referenced application is respectfully solicited.

Amendment to the Specification

Paragraph **[0001.1]** has been added to note the relationship of the current application to co-pending U.S. Patent Applications 10/103,671 and 10/081,953, which were filed concurrently or after the present application. It is respectfully submitted that the addition of this information to the specification of the above-referenced application does not introduce new matter into the above-referenced application.

Rejections under 35 U.S.C. § 102(b)

Dopson

Claims 1-16 and 18-23 have been rejected under 35 U.S.C. § 102.

A claim is anticipated only if each and every element, as set forth in the claim, is found, either expressly or inherently described, in a single reference which qualifies as prior art under 35 U.S.C. § 102. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). That single reference must show the identical invention *in as complete detail* and *in the same arrangement as that contained in the claim. Net MoneyIn, Inc. v. Verisign,* 545 F.3d 1359, 1369-70 (Fed. Cir. 2008) (emphasis supplied); *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Dopson

Claims 1-16 and 19-23 have been rejected under 35 U.S.C. § 102(e) for reciting subject matter that is purportedly anticipated by the subject matter described in U.S. Patent Application Publication 2002/0044942A1 of Dopson (hereinafter "Dopson").

The Office's indication that the 35 U.S.C. § 102(e) rejection based on Dopson may be overcome by filing an affidavit in accordance with the requirements 37 C.F.R. § 1.131 is gratefully acknowledged. Such an affidavit will be prepared and executed when all further issues in the above-referenced application have been resolved.

Rejections under 35 U.S.C. § 103(a)

Claims 1-16 and 18-22 stand rejected under 35 U.S.C. § 103(a) for being directed to subject matter that is purportedly unpatentable over the subject matter taught by U.S. Patent 5,080,895 to Tokoro (hereinafter "Tokoro"), in view of teachings from U.S. Patent 5,840,700 to Kirkpatrick (hereinafter "Kirkpatrick").

There are several requirements in establishing a *prima facie* case of obviousness against the claims of a patent application. All of the limitations of the claim must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974); *see also* MPEP § 2143.03. Even then, a claim "is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007). The Office must also establish that one of ordinary skill in the art would have had a reasonable expectation of success that the purported modification or combination of reference teachings would have been successful. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). There must also "be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.*, quoting *In re Kahn*, 441, F.3d 977, 988 (Fed. Cir. 2006). That reason must be found in the prior art, common knowledge, or derived from the nature of the problem itself, and not based on the Applicant's disclosure. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006). A mere conclusory statement that one of ordinary skill in the art would have been motivated to combine or modify reference teachings will not suffice. *KSR* at 1396.

It has been asserted that Tokoro "suggests exposure to pathogens including pollen, bacteria, viruses, mold, allergens, blood from affected animals, sperm and toxins." Office Action of December 4, 2009, pages 4-5; *see also* Tokoro, col. 4, lines 46-57. From this, the Office reasons that Tokoro suggests the use of virtually any antigen of choice for the production of a substance containing a transfer factor-like component. Office Action of December 4, 2009, pages 5-6. Actually, Tokoro expressly teaches that "[t]he antigen may be any substance to which the immune system of an animal will respond..." Col. 4, lines 50-52. Tokoro does not, however, provide any teaching or suggestion that the *T cell-mediated* part of the animal's immune system must respond to the antigen.

In fact, as has already been established, none of the specific bacterial antigens that have been identified by Tokoro is capable of causing an animal's immune system to elicit a T cell-mediated immune response. In view of that particular limitation on Tokoro's teachings, it would also be reasonable for one of ordinary skill in the art to conclude that various antigens from non-bacterial sources (*e.g.,* pollen, viruses, mold, allergens, blood from affected animals, sperm and toxins) may also be capable of causing the immune system of an animal to respond, but incapable of causing an animal to elicit a T cell-mediated immune response. As those of ordinary skill in the art are aware, a T cell-mediated immune response is prerequisite to the production of transfer factor.

In view of the foregoing, it is apparent that chickens that were exposed to the specific antigens taught by Tokoro did not produce transfer factor in response to those antigens. Instead, they purportedly produced a substance that Tokoro refers to as "transfer factor-like component." The distinction between transfer factor, as recited by independent claims 1 and 20, and the "transfer factor-like component" of Tokoro has already been established. At the time the application from which Tokoro issued was filed, the characteristics of transfer factor were well established—transfer factor was known to be produced in a T cell-mediated immune response to an antigen and those of ordinary skill in the art had some understanding of its immunological functions. The immunological functions and other characteristics of the "transfer factor-like component" of Tokoro, in contrast, were not known at that time. Col. 7, lines 44-47.

As of the filing date of the application from which Tokoro issued, and as of the date to which a claim for priority has been made in the above-referenced application, blood cells (*e.g.,* leukocytes, lymphocytes, or lymphoid cells) were the only known source of transfer factor. Thus, one of ordinary skill in the art wouldn't have been able to predict that transfer factor could be obtained from eggs. Further, in view of the fact that the specific antigens disclosed by Tokoro wouldn't have caused chickens to elicit a T cell-mediated immune response, it is apparent that the chickens wouldn't have necessarily, or inherently, produced transfer factor. As such, transfer factor wouldn't have inherently been present in eggs laid by those chickens.

The teachings of Kirkpatrick relate to methods for substantially purifying transfer factors, including transfer factors that are specific for herpes simplex viruses, such as the Epstein-Barr Virus (EBV). According to Kirkpatrick, transfer factors "can be extracted from lymphoid cells of humans and certain other animals..." Col. 1, lines 49-53. Kirkpatrick provides no teaching or suggestion that transfer factor may be obtained from any source other than blood cells, let alone from eggs.

It is respectfully submitted that there would have been no apparent reason under any of the rationales set forth by M.P.E.P. § 2143 for one of ordinary skill in the art to have combined teachings from Tokoro and Kirkpatrick in the manner that has been asserted. In particular, it is respectfully submitted that one of ordinary skill in the art wouldn't have been able to predict the methods recited by any of claims 1-16 or 18-22; *i.e.,* methods for causing treated animals to elicit T cell-mediated immune responses by administering an extract consisting of water soluble proteins of egg yolk, which include transfer factor, to the treated animal. As noted above, neither Tokoro nor Singh provides any teaching or suggestion the eggs may include (either expressly or inherently) transfer factor. Thus, the Office has not met the requirements of any of the seven exemplary rationales set forth by M.P.E.P. § 2143 to establish a finding that one of ordinary skill in the art could have predicted that the administration of an extract that consists of water soluble proteins of egg yolk, including transfer factor, to a treated animal could be used to cause the treated animal to elicit a T cell-mediated immune response. Therefore, the Office has not established a *prime facie* case of obviousness against either independent claim 1 or independent

claim 20, as would be required to maintain the 35 U.S.C. § 103(a) rejections of these claims, and of their dependent claims 2-19, 21, and 22.

Allowable Subject Matter

The indication that claim 23 is drawn to allowable subject matter is noted with appreciation. Claim 23 has not yet been amended to independent form, as independent claim 1, from which claim 23 depends, is believed to be allowable.

CONCLUSION

It is respectfully submitted that each of claims 1-23 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,

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